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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/840,722 | 04/23/2001 | Michael C. MacLeod | UTSC:607USC1 | 5071 |

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EXAMINER

WHISENANT, ETHAN C

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,722

Applicant(s)

MACLEOD ET AL.

Examiner

Ethan Whisenant, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,20,21,23-29,36-76 and 85-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,20,23,24,27-29,36-50,71,72,85 and 87-89 is/are rejected.
- 7) ☐ Claim(s) 21, 25-26, 51-70, 73-76 and 86 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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NON-FINAL REJECTION

1. The applicant's Response (filed 06 JUN 03) to the Office Action (mailed 12 MAR 03) has been entered. Following the entry of the claim amendment(s), **Claim(s) 3-4,20-21, 23-29, 36-76 and 85-89** is/are pending in this application. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

DOUBLE PATENTING REJECTIONS WITHDRAWN

2. In light of the applicant's properly filed terminal disclaimer, all of the double patenting rejections which relied on US 6,221, 600 have been withdrawn.

35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

CLAIM REJECTIONS UNDER 35 USC § 102

- 4.** Claim(s) 20, 23-24, 27-29, 36-38, 45-46, 50, 71-72, 85, and 87-89 is/are rejected under 35 U.S.C. 102(e) as being anticipated by Kuipier et al. [US 5,874,215 (1999)].

Kuipier et al. teach a method of subjecting DNA molecules to a DNA synthesis reaction which comprises all of the limitations recited in Claim 20, 23-24, 27-29, 36-38, 45-46, 50, 71-72 and 85. Note especially Figures 10-11. As regards the limitations in Claims 23-24, see at least, for example, Claim 10. In addition, Kuipier et al. teach a primer molecule/population of primer molecules comprising the limitations recited in Claims 87-89. Note at least, for example, Figures 10-11.

35 USC § 103

- 5.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 6.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

7. **Claim(s) 3-4** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuipier et al. [US 5,874,215 (1999)].

Claim 3 is drawn to an embodiment of Claim 20 wherein said DNA is non-genomic DNA.

Claim 4 is drawn to an embodiment of Claim 20 wherein said DNA is cDNA.

Kuipier et al. teach all of the limitations of Claim 3 except these authors do not explicitly teach analyzing non-genomic DNA and/or cDNA. However, as these types of DNA were well known at the time of the invention, it would have been, absent an unexpected result, *prima facie* obvious to one of ordinary skill in the art at the time of the invention to analyze cloned DNA and/or cDNA and/or cloned cDNA using the method disclosed by Kuipier et al. Absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

8. **Claim(s) 39-44 and 47-49** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuipier et al. [US 5,874,215 (1999)] as applied against Claim 36 above and further in view of Matthews et al. (1988).

Claim 39 is drawn to an embodiment of Claim 36 wherein said label is a chromophore.

Claim 40 is drawn to an embodiment of Claim 36 wherein said label is a fluorphore. **Claim 41** is drawn to an embodiment of Claim 36 wherein said label is an affinity label. **Claim 42** is drawn to an embodiment of Claim 36 wherein said label is a dye. **Claim 43** is drawn to an embodiment of Claim 37 wherein the 5' end of said primer comprises an amino moiety and a fluorphore is covalently attached thereto by the reaction of a succinimido ester of the fluorphore to the 5' modified is a dye. **Claim 44** is drawn to an embodiment of Claim 40 wherein the fluorphore is selected from a defined group which includes Texas Red.

Kuipier et al. teach all of the limitations of Claims 39-44 except these authors do not explicitly teach using the different labels recited. However, as all of the different recited were well known at the time of the invention as evidenced by Matthews et al. it would have been, absent an unexpected result, *prima*

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facie obvious to one of ordinary skill in the art at the time of the invention to use any of the labels recited to detect the amplified products of Kuipier et al. Absent an unexpected result, the substitution of one known reagent with known properties for a second well known reagent with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 47 is drawn to an embodiment of Claim 45 wherein said analysis of products is by capillary gel electrophoresis. **Claim 48** is drawn to an embodiment of Claim 45 wherein said analysis of products is by mass spectrophotometry. **Claim 49** is drawn to an embodiment of Claim 45 wherein said analysis of products is by energy transfer.

Kuipier et al. teach all of the limitations of Claims 47-49 except these authors do not explicitly teach using the different analysis methods recited. However, as all of the different analysis methods recited were well known at the time of the invention, it would have been, absent an unexpected result, *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use any of the analysis methods recited to detect the amplified products of Kuipier et al. Absent an unexpected result, the substitution of one known method with known properties for a second well known method with known properties is routine in the art. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

CLAIM REJECTIONS UNDER 35 USC § 102/103

9. Claim(s) **87-89** is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Senapathy [US 5,994,058 (1999)] for the reason of record.

10. Claim(s) **87-89** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Silver et al. [US 5,104,792 (1992)] for the reason of record.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

11. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are not deemed to be persuasive. The applicant argues that since the claims as amended recite that the primer molecule has a predetermined 5' sequence "that is prepared to incorporate a sequence that anneals to a predetermined linker sequence" this makes the claims novel and unobvious over Senapathy [US 5,994,058 (1999)] and/or Silver et al. [US 5,104,792 (1992)]. The limitations added are simply additional intended use limitations. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The primers taught by Senapathy and/or Silver et al. are capable of performing the intended use given the proper nucleic acid sequence. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For example, look at Column 3 line 55-57 of Silver et al. and note the five nucleotides just 5' of the region comprising the 3' random nucleotides. This sequence 5'- GACTCNNNN-3' will, if provided a linker sequence of 5' - XXXXGAGTC- 3' anneal thereto. Therefore it can be said that the primers taught by Senapathy and/or Silver et al. are capable of performing the intended use.

CLAIM OBJECTIONS

12. Claim(s) **21, 25-26, 51-70, 73-76 and 86** is /are objected to because it is dependent upon a rejected independent base claim.

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CONCLUSION

13. Claim(s) 3-4, 20-21, 23-29, 36-76 and 85-89 is/are rejected and/or objected to for the reason(s) set forth above.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



**ETHAN WHISENANT
PRIMARY EXAMINER**